

### REMARKS

Claims 1, 3, 5, 13, 17, 18, 29, 34, 40 and 46 have been amended and claims 4, 7 and 8 have been canceled without prejudice. Claims 1 – 3, 5 – 6 and 9 - 51 remain pending in the application. Clean copies of the remaining pending claims are attached hereto. The Examiner is respectfully requested to re-examine the claims and thereafter allow the application.

This amendment is being submitted on Tuesday September 4, 2001 with a petition for and the accompanying payment of the requisite fee for a three month extension of time. Since the three month extension of time date was September 2, 2001, a Sunday, and since the following Monday, September 3, 2001 was a Federal holiday, the applicant claims the benefit of 37 C.F.R. 1.7(a) for the filing of this Amendment.

Submitted herewith is an affidavit from the applicant setting forth the particulars of the experimental use associated with the development and continuing development of certain aspects of at least some parts and claims of the claimed invention. Also submitted herewith is a Supplemental Information Disclosure Statement.

Claims 3 – 5 stand objected to because claim 3 has two adjacent phrases of “step of”. The second occurrence of “step of” has been deleted. With this amendment it is respectfully submitted that the Examiner’s objection to claim 3 is traversed.

Claims 1 – 51 stand rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. In particular, with respect to claims 1, 34, 40 and 46, the Examiner has stated

that “a peripheral nerve” is vague and has suggested to replace this phrase with “the peripheral nerve”. These claims have been so amended.

With respect to claim 29, the Examiner has stated that “an occipital nerve” is vague and has suggested to replace this phrase with “the occipital nerve”. This claim has been so amended.

With respect to claims 5 and 8, the Examiner has stated that the phrase “the detected level of pain” lacks an antecedent basis. Claim 8 has been canceled without prejudice but claim 5 has been amended to refer to “a level of detected pain”. It is respectfully submitted that with this amendment, the Examiner’s rejection is traversed.

With respect to claims 17 and 18, the Examiner has stated that the “to evaluate” and “to develop” render the claim indefinite. The Examiner has suggested replacing these phrases with the gerund form of “evaluate” and “develop”. Claims 17 and 18 have been so amended and have in addition added clarifying language. It is respectfully submitted that with this amendment, the Examiner’s rejection is traversed.

With respect to claims 40 and 46, the Examiner has stated that the preamble is inconsistent with the claim body. These claims have been amended to refer to the neuralgia that is emanating from the peripheral nerve and the area producing the neuralgia. It is respectfully submitted that with this amendment, the preamble is entirely consistent with the claim body and that the Examiner’s rejections is traversed.

Various groupings of the claims stand rejected under 35 U.S.C. 102(b) as being anticipated by Liss et al. and Tannenbaum. Further, various groups of claims stand rejected under 35 U.S.C. 102(e) as being anticipated by Alo et al. and Law et al. Finally, several of the

claims stand rejected under 35 U.S.C. 103(a) as being unpatentable over Law. It is respectfully submitted that the claims as amended distinguish over the cited art.

Each pending independent claim claims in part placing a lead in the fascia superior to and near the peripheral nerve that is causing pain. Both Liss et al. and Tannenbaum are TENS devices. Further, Tannenbaum teaches an electrode that penetrates the skin and is inserted into the nerve to be anesthetized (col. 6, lines 25 – 29). But, neither teaches or suggests placing a lead having at least one electrode in the fascia superior to and near the peripheral nerve causing pain.

Law et al. teaches a device to be used in conjunction with spinal cord stimulation. There is no teaching or suggestion in Law et al. to place a lead having at least one electrode in the fascia superior to and near the peripheral nerve causing pain.

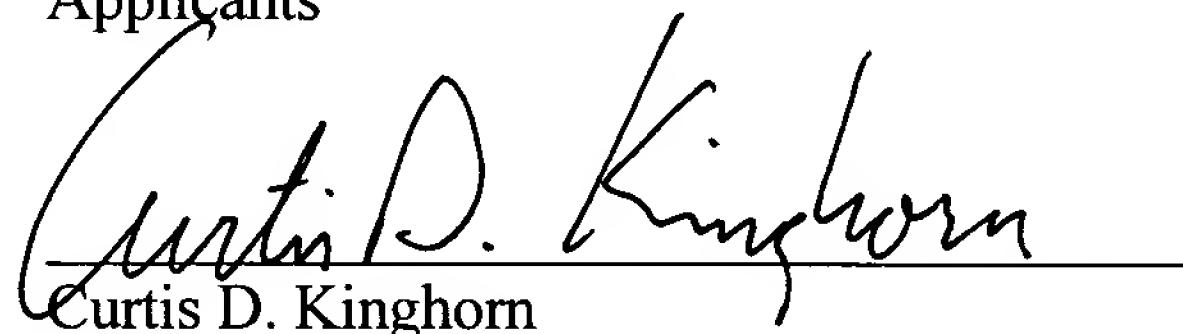
Although Alo et al. teaches peripheral nerve stimulation, Alo et al. teaches approaching the peripheral nerve by an epidural introduction of a lead near the spinal cord and the subsequent movement of the lead near the peripheral nerve (col. 5, lines 15 – 29). There is no teaching or suggestion in Alo et al. to place a lead having at least one electrode in the fascia superior to and near the peripheral nerve causing pain. In view of the foregoing, it is respectfully submitted that the cited references, alone or in combination, do not teach or suggest what the presently claimed claims claim, namely placing a lead having at least one electrode in the fascia superior to and near the peripheral nerve causing pain and then stimulating the peripheral nerve with at least the electrode placed in the fascia. Therefore, it is respectfully submitted that the claims, as amended,

distinguish over the cited references and are in condition for allowance. The Examiner is respectfully requested to re-examine the claims as amended and thereafter allow the claims.

Should the Examiner find it useful, the Examiner is requested to contact the undersigned at (763) 505-2913 with any questions or comments he may have.

Respectfully submitted,

Applicants

  
Curtis D. Kinghorn

Reg. No.33,926

MEDTRONIC, INC.

710 Medtronic Parkway, LC340

Minneapolis, MN 55432

Telephone: (763) 505-2913

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**PENDING CLAIMS AFTER AMENDMENT**

1. A method of stimulating a peripheral nerve to treat pain emanating from the peripheral nerve, the method comprising the steps of:

placing a lead having at least one electrode in fascia superior to and near the peripheral nerve that is causing pain so that at least one electrode is in the fascia; and

electrically stimulating the peripheral nerve with the at least one electrode in the fascia to cause paresthesia of the painful area.

2. The method of claim 1 wherein the step of placing a lead includes the step of placing a lead across the peripheral nerve that is causing pain.

3. The method of claim 2 wherein the step of placing a lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a lead across the peripheral nerve that is causing pain.

4. The method of claim 1 wherein the step of placing a lead in the fascia superior to the peripheral nerve includes the step of placing a lead in the fascia superior to the peripheral nerve proximal to a level of detected pain.

6. The method of claim 1 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the peripheral nerve that is causing pain.

9. The method of claim 1 further comprising the step of initially palpating the area of pain to identify the specific peripheral nerve that is causing the pain.
10. The method of claim 1 wherein the step of placing a lead includes the steps of:  
providing an introducer needle;  
subcutaneously placing the introducer needle in the fascia superior to the peripheral nerve that is causing pain.
11. The method of claim 10 wherein the step of placing a lead further includes the step of passing, when the introducer needle is in position above the peripheral nerve, the lead through the introducer needle until the lead is also in position above the peripheral nerve causing the pain.
12. The method of claim 11 further comprising the step of removing, after passing the lead through the introducer needle until the lead is also in position above the peripheral nerve causing the pain, the introducer needle leaving the lead in place above the peripheral nerve.

~~10~~<sup>10</sup>~~13~~ The method of claim ~~10~~<sup>10</sup> wherein the step of subcutaneously placing the introducer needle in the fascia superior to the peripheral nerve that is causing pain includes the step of curving the introducer needle to conform to the contour of the patient's body superior to the peripheral nerve.

14. The method of claim 1 wherein the step of placing a lead includes the step of placing dual leads.

15. The method of claim 14 further comprising the step of connecting the lead to a screening device.

16. The method of claim 15 further comprising the step of performing test electrical stimulation with the lead.

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~~17.~~ The method of claim <sup>13</sup>~~16~~ wherein the steps of performing test electrical stimulation with the lead includes the step of electrically stimulating the patient by the lead and screener device and evaluating the lead position from the patient's response to the step of electrically stimulating the patient.

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~~18.~~ The method of claim <sup>13</sup>~~16~~ wherein the step of performing test electrical stimulation with the lead includes the step of electrically stimulating the patient by the lead and screener device and developing optimal stimulation parameters based on the patient's response to the step of electrically stimulating the patient.

19. The method of claim 16 further comprising the step of receiving verbal feedback from the patient regarding paresthesia coverage of the effects of the electrical stimulation by the lead.
20. The method of claim 16 wherein the step of performing test electrical stimulation with the lead includes the step of electrically stimulating the patient with an electrical signal having an amplitude between about 0.5 to about 4.0 volts.
21. The method of claim 16 wherein the step of performing test electrical stimulation with the lead includes the step of electrically stimulating the patient with an electrical signal having a rate between about 50 Hz. to about 400 Hz.
22. The method of claim 16 wherein the step of electrically stimulating the patient with an electrical signal having a rate between about 50 Hz. to about 400 Hz. includes the step of electrically stimulating the patient with an electrical signal having a pulse width between about 90  $\mu$ sec to about 200  $\mu$ sec.
23. The method of claim 1 further comprising the steps of:  
implanting an implantable pulse generator; and  
electrically connecting the implantable pulse generator to the lead.
24. The method of claim 1 further comprising the steps of:



implanting a RF system receiver; and

electrically connecting the RF system receiver to the lead.

25. The method of claim 1 wherein the step of placing a lead near a peripheral nerve that is causing pain includes the step of placing a screening lead near a peripheral nerve that is causing pain; and

wherein the step of electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the peripheral nerve with the screening lead; and

further comprising the steps of

placing a permanent lead near the peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the permanent lead to cause paresthesia of the painful area.

26. The method of claim 25 wherein the step of placing a permanent lead includes the step of placing a permanent lead across the peripheral nerve that is causing pain.

27. The method of claim 26 wherein the step of placing a permanent lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a permanent lead across the peripheral nerve that is causing pain.

28. The method of claim 25 wherein the step of placing a permanent lead includes the step of subcutaneously placing a permanent lead near the peripheral nerve that is causing pain.

~~26~~<sup>29</sup>. A method of stimulating an occipital nerve to treat occipital neuralgia comprising the steps of:

placing a lead having at least one electrode in fascia superior to and near the occipital nerve that is causing pain so that at least one electrode is in the fascia;

electrically stimulating the occipital nerve with the at least one electrode in the fascia to cause paresthesia of the painful area.

30. The method of claim 29 wherein the step of placing a lead includes the step of placing a lead across the occipital nerve that is causing pain.

31. The method of claim 30 wherein the step of placing a lead across the occipital nerve that is causing pain includes the step of subcutaneously placing a lead across the occipital nerve that is causing pain.

32. The method of claim 29 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the occipital nerve that is causing pain.

33. The method of claim 29 wherein the step of placing a lead near an occipital nerve that is causing pain includes the step of subcutaneously placing a lead at the level of C1 transversely across the base of the occipital nerve trunk and wherein the step of electrically stimulating the occipital nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the occipital nerve trunk.

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34. A method of stimulating a peripheral nerve to treat pain emanating from the peripheral nerve, the peripheral nerve chosen from a group consisting of a supraorbital nerve, a clunial nerve, an ilioinguinal nerve, a median nerve, an ulnar nerve and a sciatic nerve, the method comprising the steps of:

placing a lead having at least one electrode in fascia superior to and near the peripheral nerve that is causing pain so that at least one electrode is in the fascia; and

electrically stimulating the peripheral nerve with the at least one electrode in the fascia to cause paresthesia of the painful area.

35. The method of claim 34 wherein the step of placing a lead includes the step of placing a lead across the peripheral nerve that is causing pain.

36. The method of claim 35 wherein the step of step of placing a lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a lead across the peripheral nerve that is causing pain.

37. The method of claim 34 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the peripheral nerve that is causing pain.

38. The method of claim 34 wherein the step of placing a lead near a peripheral nerve that is causing pain includes the step of placing a screening lead near a peripheral nerve that is causing pain; and

wherein the step of electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the peripheral nerve with the screening lead to cause paresthesia of the painful area.

39. The method of claim 38 further comprising the steps of:

placing a permanent lead near the peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the permanent lead to cause paresthesia of the painful area.

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40. A method of stimulating a peripheral nerve to treat neuralgias emanating from the peripheral nerve, the method comprising the steps of:

placing a lead having at least one electrode in fascia superior to and near the peripheral nerve that is causing the neuralgia emanating from the peripheral nerve so that at least one electrode is in the fascia; and

electrically stimulating the peripheral nerve with the at least one electrode in the fascia to cause paresthesia of the area producing the neuralgia.

41. The method of claim 40 wherein the step of placing a lead includes the step of placing a lead across the peripheral nerve that is causing pain.

42. The method of claim 41 wherein the step of step of placing a lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a lead across the peripheral nerve that is causing pain.

43. The method of claim 40 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the peripheral nerve that is causing pain.

44. The method of claim 40 wherein the step of placing a lead near a peripheral nerve that is causing pain includes the step of placing a screening lead near a peripheral nerve that is causing pain; and

wherein the step of electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the peripheral nerve with the screening lead to cause paresthesia of the painful area.

45. The method of claim 44 further comprising the steps of:

placing a permanent lead near the peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the permanent lead to cause paresthesia of the painful area.

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46.

A method of stimulating a peripheral nerve to treat neuralgias emanating from the peripheral nerve, the neuralgias chosen from a group consisting of post herpetic neuralgia, chronic deafferentation pain, chronic peripheral nerve pain, post craniotomy pain, incisional pain, clunial nerve pain, post herniorrhapy pain, localized low back or other spine pain, incisional neuroma pain, stump neuroma pain, incisional scar pain, deafferentation pain, chronic peripheral nerve pain, sciatic neuralgia, medial neuralgia and ulnar neuralgia , the method comprising the steps of:

placing a lead having at least one electrode in fascia superior to and near the peripheral nerve that is causing the neuralgia emanating from the peripheral nerve so that at least one electrode is in the fascia; and

electrically stimulating the peripheral nerve with the at least one electrode in the fascia to cause paresthesia of the area producing the neuralgia.

47. The method of claim 46 wherein the step of placing a lead includes the step of placing a lead across the peripheral nerve that is causing pain.

48. The method of claim 47 wherein the step of placing a lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a lead across the peripheral nerve that is causing pain.

49. The method of claim 46 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the peripheral nerve that is causing pain.

50. The method of claim 46 wherein the step of placing a lead near a peripheral nerve that is causing pain includes the step of placing a screening lead near a peripheral nerve that is causing pain; and

wherein the step of electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the peripheral nerve with the screening lead to cause paresthesia of the painful area.

51. The method of claim 50 further comprising the steps of:

placing a permanent lead near the peripheral nerve that is causing pain; and  
electrically stimulating the peripheral nerve with the permanent lead to cause paresthesia of the painful area.